IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LIMITED, Defendants.	:	Civil Action No. 04-171-KAJ **REDACTED VERSION**

PLAINTIFF GLAXO'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION PURSUANT TO FED. R. CIV. P. 56 FOR SUMMARY JUDGMENT OF PATENT INFRINGEMENT

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I. INTRODUCTION

Plaintiff Glaxo Group Limited ("Glaxo") submits this reply memorandum in support of its motion for summary judgment of infringement of U.S. Patent No. 5,068,249 ("the '249 patent"). Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Limited (collectively, "defendant" or "Teva") have answered Glaxo's motion for summary judgment of infringement. ("Answ. Br.") (D.I. 128). In support of its reply memorandum, Glaxo relies on the Declarations of Oren D. Langer[1] and Bradley D. Anderson, Ph.D.[2] Glaxo seeks summary judgment that defendant's generic drug product, REDACTED infringes Glaxo's '249 patent under the doctrine of equivalents.

II. SUMMARY OF ARGUMENT

Defendant's answering brief fails to present evidence sufficient to create any genuine issue of material fact in the face of

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The conclusory statements of defendant's witness are insufficient to defeat summary judgment. *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1353

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1 "Langer Decl." refers to the "Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief and Summary Judgment Motions on U.S. Patent No. 5,068,249" filed on June 30, 2006. (D.I. 99 (Exhibits 1-25) and D.I. 100 (Exhibits 26-48)). "Langer Suppl. Decl." refers to the "Supplemental Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Answering Brief to Teva's Motion for Summary Judgment of Non-Infringement" filed on July 28, 2006. (D.I. 124). "Langer 2d Suppl. Decl." refers to the "Second Supplemental Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Reply Memorandum in Support of its Motion for Summary Judgment of Infringement" submitted herewith.

2 "Anderson Decl." refers to "Declaration of Bradley D. Anderson, Ph.D., in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief on U.S. Patent No. 5,068,249" filed on June 30, 2006. (D.I. 98).

(Fed. Cir. 2001) (summary judgment cannot be defeated by "conclusory statements of counsel or a witness."). The following evidence of patent infringement is not in dispute:

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[3] "Anderson Opening Rpt." refers to "Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Expert Witness Report Concerning The Issue of Infringement of Glaxo's '249 Patent" attached as Exhibit A to the Anderson Declaration filed on June 30, 2006. (D.I. 98).

[4] "Kibbe Dep." refers to the deposition testimony of Teva expert witness Arthur H. Kibbe, Ph.D., taken in this matter on May 16, 2006 and attached as Exhibit 7 to the Langer 2d Suppl. Decl. submitted herewith.

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- The *Pharmadyne* court,

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REDACTED *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 286 and 291 (D. Md. 1998).

Glaxo has met its burden of proof in establishing infringement of the '249 patent claims. Defendant, which has no evidence in rebuttal, relies on misstatements of the law to prop up the legally irrelevant "facts" it puts forth. Infringement of the '249 patent claims does not require proof that defendant

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See Graver Tank & Manufacturing Co., Inc. v. Linde Air Products Co., 339 U.S. 605, 608 (1950); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). The '249 patent claims do not require only one specific type

of stability comparison to prove an enhancement in ranitidine stability. (Please see Plaintiff Glaxo Group Limited's Answering Brief to Defendant's Opening Brief In Support Of Its Claim Construction at pp. 13-17, D.I. 122). The doctrine of prosecution history estoppel does not apply because the "ethanol" limitation was never amended to exclude equivalent types of ranitidine stabilizers. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002). (*See also* Plaintiff Glaxo's Answering Brief To Defendant's Motion For Summary Judgment Of Non-Infringement at 11-22, D.I. 123). Even under the rebuttable presumption test of *Festo*, the addition of the "stabilizing effective amount" limitation to claim 1 of the '249 patent was tangential to

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Glaxo respectfully requests that its motion for summary judgment of patent infringement be granted.

III. ARGUMENT

A. Defendant's Conclusory Denials And Legally Irrelevant Facts Are Insufficient To Defeat Summary Judgment

Defendant's answering brief cites legally irrelevant facts and fails to cite specific evidence to create a genuine issue of material fact necessitating a trial on the issue of patent infringement. Fed. R. Civ. P. Rule 56(e). "The party opposing the [summary judgment] motion must point to an evidentiary conflict created on the record at least by a counter statement of a

fact or facts set forth in detail in an affidavit by a knowledgeable affiant. Mere denials or conclusory statements are insufficient." *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984); *see also Biotec*, 249 F.3d at 1353. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Defendant fails to point to any relevant evidentiary conflict. Glaxo submits, therefore, that it is entitled to summary judgment of patent infringement.

B. Defendant's Assertions Consist Of Unsupported, Conclusory Opinions And Denials

1. Professor Kibbe's Conclusory Opinions Are Not "Facts" And Defendant's Reliance On ¶¶ 45-52 Of Professor Kibbe's Rebuttal Report Is Fundamentally Flawed

Professor Kibbe's conclusory opinions from his rebuttal report attacking Professor Anderson's data and analysis (Answ. Br. at 4-10) have no evidence to support them.

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This is consistent with the *Pharmadyne* court's finding that "ethanol enhances the chemical stability of ranitidine hydrochloride by retarding the degradation rate of ranitidine through hydrolysis," and that "propylene glycol functions to stabilize ranitidine hydrochloride in the accused product in a manner similar to ethanol stabilizing the compound in the '249 patent." *Pharmadyne*, 32 F. Supp. 2d at 285.

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was also rejected by the *Pharmadyne* court as legally irrelevant, because there is no requirement "to understand the exact mechanics of how ethanol stabilizes ranitidine hydrochloride." *Pharmadyne*, 32 F. Supp. 2d at 285-86 (citing *Micro Motion, Inc. v. Exac Corp.*, 741 F. Supp. 1426, 1441 (N.D. Cal. 1990)); *see also Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed. Cir. 1983); *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999). The only conclusion to be drawn from the evidence is that Professor Kibbe agrees with Professor Anderson's analysis of the stability test data demonstrating

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Professor Kibbe leaves defendant with nothing more than unsupported remarks, guesses, and naked opinions.

2. **In Defendant's Accused Product Is Functionally Equivalent To The Claimed Percentages In Claims 2, 3, 11 And 12 Of The '249 Patent**

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3. Mrs. Bird's Memorandum Is Not Inconsistent With Dr. Hempenstall's Declaration Or Professor Anderson's Analysis

The inferences defendant draws from the memorandum written by Mrs. Bird (Defendant's Answ. Br. to Glaxo's motion dismissing the inequitable conduct allegations, D.I. 125, at 15) are puzzling.

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[5] "Anderson Suppl. Rpt." refers to "Bradley D. Anderson, Ph.D. Fed. R. Civ. P. 26(a)(2) Supplemental Expert Witness Report Responsive to Prof. Kibbe's Deposition Testimony" attached as Exhibit C to the Anderson Declaration. (D.I. 98).

[6] "Anderson Dep." refers to the deposition testimony of Glaxo expert witness, Bradley D. Anderson, Ph.D., taken in this matter on June 8, 2006.

[7] Please see pp. 14-17 of Glaxo's Reply Brief In Support of its Motion For Summary Judgment Dismissing Defendant's Affirmative Defenses and Corresponding Counterclaim (continued)

4. Like Pharmadyne, Defendant Has Not Come Forward With Any Evidence To Contradict Professor Anderson's Evidence

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Defendant fails to support its claim that "ample evidence suggest[s] that other components" enhance the stability of ranitidine in its ANDA product. (Answ. Br. at 8). If Teva had such evidence "it should have produced such evidence." *See Pharmadyne*, 32 F. Supp. 2d at 291 (addressing the identical claim and lack of evidence).

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[9] "Kibbe Rpt." refers to the Expert Report of Professor Arthur H. Kibbe submitted on March 14, 2006.

[10] "Anderson Rebuttal Rpt." refers to the Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Rebuttal Expert Witness Report attached as Exhibit B to the Anderson Declaration submitted on June 30, 2006. (D.I. 98).

C. Glaxo Has Proved All That Is Required For A Finding of Patent Infringement: There Is No Claim Limitation Requiring The Use Of Ethanol As A Solvent And Antimicrobial Preservative, Nor Is One Specific Type Of Stability Comparison Required To Prove Infringement

1. The Use Of Ethanol Or An Equivalent To Enhance Ranitidine Stability Is The Only Functional Requirement For Purposes of Infringement

Neither the '249 patent claims nor the intrinsic evidence support defendant's search for "three functions" of ethanol and (Answ. Br. at 5-6, 19-20). Rather, the question to be decided is whether the accused product accomplishes substantially the same function, in substantially the same way to achieve substantially the same result as the claimed invention. *See Graver Tank*, 339 U.S. at 608; *Warner-Jenkinson*, 520 U.S. at 40. The claim limitations are the measure of infringement, and additional unclaimed functions - REDACTED are neither relevant nor required elements of proof as suggested by defendant.[11] *See Graver Tank*, 339 U.S. at 608; *Warner-Jenkinson*, 520 U.S. at 40.

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The '249 patent claims "a stabilizing effective amount of ethanol." There is no antimicrobial preservative or solvent function claimed for ethanol, nor does defendant argue that any claim limitation in the '249 patent claims should be construed to include an antimicrobial preservative or solvent function of ethanol. (Please see defendant's opening claim construction brief, D.I. 101 at 3). During prosecution of the applications that led to the '249 patent, the applicant specifically acknowledged and distinguished the claimed invention from the prior art

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[11] This is an incorrect statement of law because it is only the claimed function of ethanol as a ranitidine stablilizer that Glaxo must prove is in defendant's accused product. *See Graver Tank*, 339 U.S. at 608; *Warner-Jenkinson*, 520 U.S. at 40.

functions of using ethanol as an antimicrobial preservative or solvent. ('249 File History at G000205, Langer Decl., Ex. 10).

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2. Evidence of Copying Is Evidence of Infringement Under The Doctrine of Equivalents

Defendant misconstrues Glaxo's citation to the Federal Circuit's decision in *Warner-Jenkinson* and attempts to sow confusion with respect to the doctrine of equivalents. (Answ. Br. at 27-29, citing *Hilton Davis Chemical Co. v. Warner-Jenkinson Co. Inc.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995)). Patent infringement is not an intentional tort. However, defendant ignores Supreme Court and Federal Circuit precedent recognizing that the actions of "the unscrupulous copyist" can properly be considered when determining whether an accused product infringes under the doctrine of equivalents. *Id.*; *see also, e.g., Warner-Jenkinson*, 520 U.S. at 36; *Festo*, 535 U.S. at 726-27 ("a patent protects its holder against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patent invention."); *Toro Co. v. White Consolidated Industries, Inc.*, 266 F.3d 1367, 1370 (Fed Cir. 2001) (citing *Graver Tank*, 339

[12] "Mazumder Dep." refers to the deposition testimony of Teva 30(b)(6) witness Subrata Mazumder, taken in this matter on January 12, 2006.

U.S. at 607 referring to the "unscrupulous copyist [who] make[s] unimportant and insubstantial changes and substitutions in the patent" as justification for the doctrine of equivalents); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 130 (D. Mass. 2003) ("The doctrine of equivalents was designed to provide patent applicants the wiggle room that claim language alone cannot, thus protecting patentees from copyists who make insubstantial changes.").

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(Please see Glaxo's Opening Br. at 10-14).

This is relevant and material evidence supporting a finding of infringement under the doctrine of equivalents.

3. The '249 Patent Claims Do Not Require Only One Specific Type of Stability Comparison To Prove Infringement

Defendant erects yet another straw man, without citation, arguing that the '249 patent requires a head-to-head comparison

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The '249 patent claims, specification and file history do not require such a claim limitation, and there is no legal or evidentiary support for defendant's position.

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[13] U.K. Patent Application GB 2142820A, cited at Col. 1:23-38 of the '249 patent.

Pharmadyne's ANDA product infringed the '249 patent claims. *Pharmadyne*, 32 F. Supp. 2d at 285-87. A complete discussion of Glaxo's position is contained in Plaintiff Glaxo Group Limited's Answering Brief To Defendant's Opening Brief In Support Of Its Claim Construction, D.I. 97, at 13-17.

D. Prosecution History Estoppel Does Not Apply Here

The '249 patent applicant never amended the "ethanol" claim limitation to exclude equivalent types of ranitidine stabilizers. Defendant's amendment-based estoppel argument, therefore, does not apply to this case. *See Festo*, 535 U.S. at 738. Defendant also misapplies the *Festo* test for rebutting an allegation of amendment-based estoppel. The doctrine of prosecution history estoppel will not apply if either 1) the relevant claim amendment was tangential to the equivalent in question, or 2) the equivalent in question was unforeseeable at the time of the amendment. *Id.* at 738; *Amgen*, 287 F. Supp. at 140. The facts of this case support both conditions, thus the doctrine of prosecution history estoppel does not apply here. Glaxo's position is thoroughly addressed at pp. 11-22 of Plaintiff Glaxo's Answering Brief to Defendant's Motion For Summary Judgment of Non-Infringement. (D.I. 123).

E. The REDACTED Is Still Missing – Glaxo's Request For An Adverse Inference Of Patent Infringement Is Well Supported

REDACTED This is a remarkable assertion, made without a supporting declaration or any other evidentiary support, especially considering the numerous requests, depositions, and Court conferences that have occurred regarding identification and production of this report. Even though Glaxo and the Court were previously told that defendant searched for and could not locate the REDACTED and even though the deposition testimony of numerous fact witnesses and Rule 30(b)(6) designees

failed to identify and locate the requested document, defendant now claims that three pages (numbered three through five) of the document were produced long ago and now it cannot understand what the fuss is about. Glaxo submits that an adverse inference on the issue of patent infringement is warranted under these circumstances. *See Liafil, Inc. v. Learning 2000, Inc.*, Civ. Nos. 01-599 and 01-678, 2002 U.S. Dist. LEXIS 24803, *9 (D. Del. December 23, 2002) ("Where the nature of the alleged breach of a discovery obligation is the non-production of evidence, the court has broad discretion in fashioning an appropriate sanction.") (attached as Exhibit A to D.I. 95).

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[14] "Fernandes Dep." refers to the deposition testimony of John Fernandes taken in this matter on March 3, 2006.

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[15] "Szederkenyi Dep." refers to the deposition testimony of Tamas Szederkenyi taken in this matter on May 19, 2005.

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16 "Massucci Dep." refers to the deposition testimony of Angelique Massucci, taken in this matter on January November 2, 2005.

17 "Mattiuz Dep." refers to the deposition testimony of defendant's Rule 30(b)(6) designee Annette Mattiuz, taken in this matter on November 3, 2005.

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2. Defendant's New Claim Of Production Is Contradicted By Its Counsel's Earlier Statements

The claim now made in defendant's answering brief is contrary to its counsel's previous statements. During a June 30, 2005 telephone conference, defendant's counsel advised the Court, in reference to the , and other documents identified by Glaxo's counsel, that "we don't have the documents in-house." (Transcript at 10:11-14) (D.I. 57). In correspondence dated October 4, 2005, defendant's counsel advised Glaxo that defendant has "been unable to locate a and that they "have not found one." (Langer 2d Suppl. Decl., Ex. 15). The discovery record indicates that the

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[18] "Wrigley Dep." refers to the deposition testimony of defendant's Rule 30(b)(6) witness Margaret Wrigley, taken in this matter on March 22, 2006.

REDACTED a document prepared in the normal course of business by defendant, has not been produced to Glaxo. It is apparent that defendant has either purposefully not looked for the Report, or, as a result of negligence, has destroyed it. Glaxo's request for the sanction of an adverse inference on the issue of patent infringement is especially appropriate under these circumstances.

IV. CONCLUSION

For the reasons stated above and in Glaxo's opening brief, Glaxo respectfully requests that the Court find that defendant's accused product infringes claims 1-12 of Glaxo's '249 patent under the doctrine of equivalents.

Dated: August 25, 2006

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CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2006, I filed **PLAINTIFF GLAXO'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION PURSUANT TO FED. R. CIV. P. 56 FOR SUMMARY JUDGMENT OF PATENT INFRINGEMENT** with the Clerk of Court and will hand deliver such filing to the following:

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